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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,633	10/14/2003	Michael S. Kopreski	00-1312-L	5239

7590 12/15/2006

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,633	KOPRESKI, MICHAEL S.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *5-10 and 17-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-22 and species (2) (her-2/neu-directed therapy, claims 11-16) in the reply filed on September 28, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 1-4 and 11-16 will be examined.

Specification

2. The disclosure is objected to because of the following informalities: (1) since case 09/155,152 now is US Patent No. 6,329,179, applicant is required to update this information in the first sentence of the specification. Although case 09/965,515 is a continuation of this instant case, applicant does not claim priority for the case 09/965,515 in the first sentence of the specification.

Appropriate correction is required.

Claim Objections

3. Claim 1 is objected to because of the following informality: "signal" in line 3 of step b) should be " a signal".

4. Claims 2-4, 12, and 15 are objected to because of the following informality: "A method" in line 1 should be "The method".

5. Claim 14 is objected to because of the following informality: ""h2/neu" in line 1 should be "her2/neu".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Scope of Enablement

Claims 1-4 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting her-2/neu RNA in plasma or serum in certain human cancer patients, does not reasonably provide enablement for (1) using the methods recited in claims 1 and 2 for detecting, diagnosing, evaluating or monitoring any kind of caner or premaligant disease by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B 1 RNA, or any combination thereof in a non-cellular fraction of any kind of bodily fluid from a human; (2) using the methods recited in claims 3 and 4 for extracting an RNA species from a non-cellular fraction of any kind of bodily fluid from any kind of human or animal using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA; (3) using the methods recited in claims 11-13 for selecting a human or animal for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or

cDNA or epidermal growth factor RNA or cDNA; and (4) using the methods recited in claims 14-16 for monitoring response in a human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that: (1) the methods recited in claims 1 and 2 can be used for detecting, diagnosing, evaluating or monitoring any kind of caner or premaligant disease by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA, or any combination thereof in a non-cellular fraction of any kind of bodily fluid from a human; (2) the methods recited in claims 3 and 4 can be used for extracting an RNA species from a non-cellular fraction of any kind of

bodily fluid from any kind of human or animal using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA; (3) the methods recited in claims 11-13 can be used for selecting a human or animal for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA; and (4) the methods recited in claims 14-16 can be used for monitoring response in a human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether: (1) the methods recited in claims 1 and 2 can be used for detecting, diagnosing, evaluating or monitoring any kind of caner or premaligant disease by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA, or any combination thereof in a non-cellular fraction of any kind of bodily fluid from a human; (2) the methods recited in claims 3 and 4 can be used for extracting an RNA species from a non-cellular fraction of any kind of bodily fluid from any kind of human or animal using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA; (3) the methods recited in claims 11-13 can be used for selecting a human or animal for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA; and (4) the methods recited in claims 14-16 can be used for monitoring response in a

human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA.

Claims 1 and 2 are directed to a method for detecting, diagnosing, evaluating or monitoring any kind of cancer or premalignant disease in human by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA, or any combination thereof in a non-cellular fraction of any kind of bodily fluid from a human. First, since it is known that some of cancers such as Hodgkin and Hon-Hodgkin lymphoma do not have overexpression or even any expression of her-2/neu RNA (see abstract in page 574 of Arch. Pathol. Lab. Med., 126, 574-576, 2002), it is unclear how to detect, diagnose, evaluate or monitor any kind of cancer or premalignant disease in human by amplifying her-2/neu RNA. Second, since the specification does not provide guidance to show that her-2/neu RNA can be detected from any kind of bodily fluid such as urine, it is unclear how to perform the method recited in claims 1 and 2 by detecting her-2/neu RNA from any kind of bodily fluid such as urine. Third, since the specification does not provide guidance to show that epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B1 RNA can be detected in the same non-cellular fraction of a bodily fluid from a human having a cancer or premalignant disease, it is unclear how to amplify any combination of epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear ribonucleoprotein A2/B 1 RNA. Fourth, since the phrase "the human's amplified product or signal is more like the amplified product or signal from

the one or plurality of humans having cancer or premalignant disease" in step (d) of claim 1 does not indicate the degree of similarity between the human's amplified product or signal and the amplified product or signal from the one or plurality of humans having cancer or premalignant disease, it is unclear how the cancer or premalignant disease is detected, diagnosed, evaluated or monitored when the human's amplified product or signal is more like the amplified product or signal from the one or plurality of humans having cancer or premalignant disease than like the amplified product or signal from the one or plurality of humans without cancer or premalignant disease. Claim 3 is directed to a method for extracting an RNA species from a non-cellular fraction of a bodily fluid using a probe that hybridizes with said RNA species, wherein the RNA species is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B 1 RNA. Since the specification does not provide guidance to show that her-2/neu RNA exists in any kind of bodily fluid, it is unclear how to extract an RNA species from a non-cellular fraction of a bodily fluid using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA. Although claim 4 limits that the non-cellular fraction of a bodily fluid is blood plasma or serum, since the specification does not provide guidance to show that her-2/neu RNA exists in blood plasma or serum from any kind of human or animal, it is unclear how to extract an RNA species from blood plasma or serum from any kind of human or animal extract using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA. For example, since it is known that some of cancers such as Hodgkin and Hon-Hodgkin lymphoma do not have overexpression or even any expression of her-2/neu RNA (see abstract in page 574 of Arch. Pathol. Lab. Med., 126, 574-576, 2002), it is unclear how to extract an RNA species from blood

plasma or serum from a patient having Hodgkin and Hon-Hodgkin lymphoma using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA. Claims 11-13 are directed to selecting a human or animal for a her2/neu-directed therapy. Since it is known that human contains four different epidermal growth factor receptors, which have different structure (see page 2169 of Gilmour et al., Cancer Research, 61, 2169-2716, 2001), and her2/neu is one of four different epidermal growth factor receptors, it is unclear how to select a human or animal for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for any kind of human epidermal growth factor receptor RNA or cDNA. Furthermore, the specification does not provide guidance to show to select a human or animal for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for any kind of human epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA. In addition, since the specification does not provide guidance to show that epidermal growth factor receptor RNA or epidermal growth factor RNA can be detected from a non-cellular fraction of any kind of bodily fluid such as urine, it is unclear how to perform the method recited in claim 3. Claim 14 is directed to a method for monitoring response in a human or animal to a her2/neu-directed therapy. Since it is known that human contains four different epidermal growth factor receptors, which have different structure (see page 2169 of Gilmour et al., Cancer Research, 61, 2169-2716, 2001), and her2/neu is one of four different epidermal growth factor receptors, it is unclear how to monitor response in a human or animal for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for any kind of human epidermal growth factor receptor RNA or cDNA. Furthermore, the

specification does not provide guidance to show to monitor response in a human or animal for a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for any kind of human epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA. In addition, since the specification does not provide guidance to show that epidermal growth factor receptor RNA or epidermal growth factor RNA can be detected from a non-cellular fraction of any kind of bodily fluid such as urine, it is unclear how to perform the method recited in claims 15.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether the methods recited in claims 1 and 2 can be used for detecting, diagnosing, evaluating or monitoring any kind of caner or premaligant disease by amplifying a RNA species that is epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, heterogeneous nuclear ribonucleoprotein A2/B1 RNA, or any combination thereof in a non-cellular fraction of any kind of bodily fluid from a human; (2) the methods recited in claims 3 and 4 can be used for extracting an RNA species from a non-cellular fraction of any kind of bodily fluid from any kind of human or animal using a probe that hybridizes with said RNA species wherein the RNA species is her-2/neu RNA; (3) the methods recited in claims 11-13 can be used for selecting a human or animal for a her-2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA; and (4) the methods recited in claims 14-16 can be used for monitoring response in a

human or animal to a her2/neu-directed therapy by assaying quantitatively or qualitatively a non-cellular fraction of any kind of bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 2, and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 is rejected as vague and indefinite in view of the phrase "the human's amplified product or signal is more like the amplified product or signal from the one or plurality of humans having cancer or premalignant disease than like the amplified product or signal from the one or plurality of humans without cancer or premalignant disease" because the phrase "the human's amplified product or signal is more like the amplified product or signal from the one or plurality of humans having cancer or premalignant disease" does not indicate the degree of similarity between the human's amplified product or signal and the amplified product or signal from the one or plurality of humans having cancer or premalignant disease. Furthermore, since step b) of the claim does not require that primers or probes specific for said RNA species have a label, it is unclear how to produce a signal. Please clarify.

11. Claim 11 is rejected as vague and indefinite. Although the claim is directed to a method for selecting a human or animal for a her2/neu-directed therapy, from the claim, it is unclear

what is a standard for selecting a human or animal for a her2/neu-directed therapy or how to select a human or animal for a her2/neu-directed therapy. Please clarify.

12. Claim 14 is rejected as vague and indefinite. Although the claim is directed to a method for monitoring response in a human or animal to a her2/neu-directed therapy, from the claim, it is unclear how to monitor response in a human or animal for a her2/neu-directed therapy. Please clarify.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs *et al.,* (WO 90/09456, published on August 23, 1990).

Regarding claims 3 and 4, Balazs *et al.,* teach a method for extracting an RNA species (ie., the PCR product) from a non-cellular fraction of a bodily fluid (ie., blood plasma) using a probe (ie., the primers) that hybridizes with said RNA species, wherein the RNA species is epidermal growth factor receptor RNA (ie., Erbb) or c-myc RNA as recited in claim 3 and wherein the non-cellular fraction of a bodily fluid is blood plasma as recited in claim 4 (see pages 14-19).

Therefore, Balazs *et al.,* teach all limitations recited in claims 3 and 4.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-4 and 11-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-39 of U.S. Patent No. 6,916,634 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been

obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1-4 and 11-16 in this instant application are not identical to claims 25-39 of U.S. Patent No. 6,916,634 B2, claims 25-39 of U.S. Patent No. 6,916,634 B2 are directed to the same subject matter and fall entirely within the scope of claims 1-4 and 11-16 in this instant application. In other words, claims 1-4 and 11-16 in this instant application is anticipated by claims 25-39 of U.S. Patent No. 6,916,634 B2. Note that mammalian RNA species recited in claims 25 and 35 of U.S. Patent No. 6,916,634 B2 can be her-2/neu (see column 11).

17. Claims 1-4 and 11-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,759,217 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 1-4 and 11-16 in this instant application are not identical to claims 1-22 of U.S. Patent No. 6,759,217 B2, claims 1-22 of U.S. Patent No. 6,759,217 B2 are directed to the same subject matter and fall entirely within

the scope of claims 1-4 and 11-16 in this instant application. In other words, claims 1-4 and 11-16 in this instant application is anticipated by claims 1-22 of U.S. Patent No. 6,759,217 B2.

18. Claims 3 and 4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,939,671 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claims 3 and 4 in this instant application are not identical to claims 1-8 of U.S. Patent No. 6,939,671 B2, claims 1-8 of U.S. Patent No. 6,939,671 B2 are directed to the same subject matter and fall entirely within the scope of claims 3 and 4 in this instant application. In other words, claims 3 and 4 in this instant application is anticipated by claims 1-8 of U.S. Patent No. 6,939,671 B2. Note that mammalian RNA species recited in claim 1 of U.S. Patent No. 6,939,671 B2 can be her-2/neu (see column 11).

Conclusion

17. No claim is allowed.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

December 8, 2006

FRANK LU
PRIMARY EXAMINER